

107TH CONGRESS
1ST SESSION

S. 895

To amend the Internal Revenue Code of 1986 to allow a credit against income tax for research related to developing vaccines against widespread diseases and ensure that such vaccines are affordable and widely distributed.

IN THE SENATE OF THE UNITED STATES

MAY 16 (legislative day, MAY 15), 2001

Mr. KERRY (for himself and Mr. FRIST) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To amend the Internal Revenue Code of 1986 to allow a credit against income tax for research related to developing vaccines against widespread diseases and ensure that such vaccines are affordable and widely distributed.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Vaccines for the New
5 Millennium Act of 2001”.

1 **SEC. 2. CREDIT FOR MEDICAL RESEARCH RELATED TO DE-**
 2 **VELOPING VACCINES AGAINST WIDESPREAD**
 3 **DISEASES.**

4 (a) IN GENERAL.—Subpart D of part IV of sub-
 5 chapter A of chapter 1 of the Internal Revenue Code of
 6 1986 (relating to business related credits) is amended by
 7 adding at the end the following new section:

8 **“SEC. 45E. CREDIT FOR MEDICAL RESEARCH RELATED TO**
 9 **DEVELOPING VACCINES AGAINST WIDE-**
 10 **SPREAD DISEASES.**

11 “(a) GENERAL RULE.—For purposes of section 38,
 12 the vaccine research credit determined under this section
 13 for the taxable year is an amount equal to 30 percent of
 14 the qualified vaccine research expenses for the taxable
 15 year.

16 “(b) QUALIFIED VACCINE RESEARCH EXPENSES.—
 17 For purposes of this section—

18 “(1) QUALIFIED VACCINE RESEARCH EX-
 19 PENSES.—

20 “(A) IN GENERAL.—Except as otherwise
 21 provided in this paragraph, the term ‘qualified
 22 vaccine research expenses’ means the amounts
 23 which are paid or incurred by the taxpayer dur-
 24 ing the taxable year which would be described
 25 in subsection (b) of section 41 if such sub-

section were applied with the modifications set forth in subparagraph (B).

“(B) MODIFICATIONS; INCREASED INCENTIVE FOR CONTRACT RESEARCH PAYMENTS.—For purposes of subparagraph (A), subsection (b) of section 41 shall be applied—

“(i) by substituting ‘vaccine research’ for ‘qualified research’ each place it appears in paragraphs (2) and (3) of such subsection, and

“(ii) by substituting ‘100 percent’ for ‘65 percent’ in paragraph (3)(A) of such subsection.

“(C) EXCLUSION FOR AMOUNTS FUNDED BY GRANTS, ETC.—The term ‘qualified vaccine research expenses’ shall not include any amount to the extent such amount is funded by any grant, contract, or otherwise by another person (or any governmental entity).

“(2) VACCINE RESEARCH.—The term ‘vaccine research’ means research to develop vaccines and microbicides for—

“(A) malaria,

“(B) tuberculosis,

“(C) HIV, or

1 “(D) any infectious disease (of a single eti-
2 ology) which, according to the World Health
3 Organization, causes over 1,000,000 human
4 deaths annually.

5 “(c) COORDINATION WITH CREDIT FOR INCREASING
6 RESEARCH EXPENDITURES.—

7 “(1) IN GENERAL.—Except as provided in para-
8 graph (2), any qualified vaccine research expenses
9 for a taxable year to which an election under this
10 section applies shall not be taken into account for
11 purposes of determining the credit allowable under
12 section 41 for such taxable year.

13 “(2) EXPENSES INCLUDED IN DETERMINING
14 BASE PERIOD RESEARCH EXPENSES.—Any qualified
15 vaccine research expenses for any taxable year which
16 are qualified research expenses (within the meaning
17 of section 41(b)) shall be taken into account in de-
18 termining base period research expenses for pur-
19 poses of applying section 41 to subsequent taxable
20 years.

21 “(d) SPECIAL RULES.—

22 “(1) LIMITATIONS ON FOREIGN TESTING.—No
23 credit shall be allowed under this section with re-
24 spect to any vaccine research (other than human
25 clinical testing) conducted outside the United States.

1 “(2) PRE-CLINICAL RESEARCH.—No credit shall
 2 be allowed under this section for pre-clinical re-
 3 search unless such research is pursuant to a re-
 4 search plan an abstract of which has been filed with
 5 the Secretary before the beginning of such year. The
 6 Secretary, in consultation with the Secretary of
 7 Health and Human Services, shall prescribe regula-
 8 tions specifying the requirements for such plans and
 9 procedures for filing under this paragraph.

10 “(3) CERTAIN RULES MADE APPLICABLE.—
 11 Rules similar to the rules of paragraphs (1) and (2)
 12 of section 41(f) shall apply for purposes of this sec-
 13 tion.

14 “(4) ELECTION.—This section (other than sub-
 15 section (e)) shall apply to any taxpayer for any tax-
 16 able year only if such taxpayer elects to have this
 17 section apply for such taxable year.

18 “(e) CREDIT TO BE REFUNDABLE FOR CERTAIN
 19 TAXPAYERS.—

20 “(1) IN GENERAL.—In the case of an electing
 21 qualified taxpayer—

22 “(A) the credit under this section shall be
 23 determined without regard to section 38(c), and

24 “(B) the credit so determined shall be al-
 25 lowed as a credit under subpart C.

1 “(2) ELECTING QUALIFIED TAXPAYER.—For
 2 purposes of this subsection, the term ‘electing quali-
 3 fied taxpayer’ means, with respect to any taxable
 4 year, any domestic C corporation if—

5 “(A) the aggregate gross assets of such
 6 corporation at any time during such taxable
 7 year are \$500,000,000 or less,

8 “(B) the net income tax (as defined in sec-
 9 tion 38(c)) of such corporation is zero for such
 10 taxable year and the 2 preceding taxable years,

11 “(C) as of the close of the taxable year, the
 12 corporation is not under the jurisdiction of a
 13 court in a title 11 or similar case (within the
 14 meaning of section 368(a)(3)(A)),

15 “(D) the corporation provides such assur-
 16 ances as the Secretary requires that, not later
 17 than 2 taxable years after the taxable year in
 18 which the taxpayer receives any refund of a
 19 credit under this subsection, the taxpayer will
 20 make an amount of qualified vaccine research
 21 expenses equal to the amount of such refund,
 22 and

23 “(E) the corporation elects the application
 24 of this subsection for such taxable year.

1 “(3) AGGREGATE GROSS ASSETS.—Aggregate
2 gross assets shall be determined in the same manner
3 as such assets are determined under section
4 1202(d).

5 “(4) CONTROLLED GROUPS.—A corporation
6 shall be treated as meeting the requirement of para-
7 graph (2)(B) only if each person who is treated with
8 such corporation as a single employer under sub-
9 sections (a) and (b) of section 52 also meets such re-
10 quirement.

11 “(5) SPECIAL RULES.—

12 “(A) RECAPTURE OF CREDIT.—The Sec-
13 retary shall promulgate such regulations as nec-
14 essary and appropriate to provide for the recap-
15 ture of any credit allowed under this subsection
16 in cases where the taxpayer fails to make the
17 expenditures described in paragraph (2)(D).

18 “(B) EXCLUSION OF CERTAIN QUALIFIED
19 VACCINE RESEARCH EXPENSES.—For purposes
20 of determining the credit under this section for
21 a taxable year, the qualified vaccine research
22 expenses taken into account for such taxable
23 year shall not include an amount paid or in-
24 curred during such taxable year equal to the
25 amount described in paragraph (2)(D) (and not

1 already taken into account under this subpara-
 2 graph for a previous taxable year).”.

3 (b) INCLUSION IN GENERAL BUSINESS CREDIT.—

4 (1) IN GENERAL.—Section 38(b) of the Internal
 5 Revenue Code of 1986 is amended by striking
 6 “plus” at the end of paragraph (12), by striking the
 7 period at the end of paragraph (13) and inserting “,
 8 plus”, and by adding at the end the following new
 9 paragraph:

10 “(14) the vaccine research credit determined
 11 under section 45E.”.

12 (2) TRANSITION RULE.—Section 39(d) of such
 13 Code is amended by adding at the end the following
 14 new paragraph:

15 “(10) NO CARRYBACK OF SECTION 45E CREDIT
 16 BEFORE ENACTMENT.—No portion of the unused
 17 business credit for any taxable year which is attrib-
 18 utable to the vaccine research credit determined
 19 under section 45E may be carried back to a taxable
 20 year ending before the date of the enactment of sec-
 21 tion 45E.”.

22 (c) DENIAL OF DOUBLE BENEFIT.—Section 280C of
 23 the Internal Revenue Code of 1986 is amended by adding
 24 at the end the following new subsection:

1 “(d) CREDIT FOR QUALIFIED VACCINE RESEARCH
2 EXPENSES.—

3 “(1) IN GENERAL.—No deduction shall be al-
4 lowed for that portion of the qualified vaccine re-
5 search expenses (as defined in section 45E(b)) oth-
6 erwise allowable as a deduction for the taxable year
7 which is equal to the amount of the credit deter-
8 mined for such taxable year under section 45E(a).

9 “(2) CERTAIN RULES TO APPLY.—Rules similar
10 to the rules of paragraphs (2), (3), and (4) of sub-
11 section (c) shall apply for purposes of this sub-
12 section.”.

13 (d) DEDUCTION FOR UNUSED PORTION OF CRED-
14 IT.—Section 196(c) of the Internal Revenue Code of 1986
15 (defining qualified business credits) is amended by strik-
16 ing “and” at the end of paragraph (8), by striking the
17 period at the end of paragraph (9) and inserting “, and”,
18 and by adding at the end the following new paragraph:

19 “(10) the vaccine research credit determined
20 under section 45E(a) (other than such credit deter-
21 mined under the rules of section 280C(d)(2)).”.

22 (e) TECHNICAL AMENDMENTS.—

23 (1) Section 1324(b)(2) of title 31, United
24 States Code, is amended by inserting “or from sec-
25 tion 45E(e) of such Code,” after “1978,”.

1 (2) The table of sections for subpart D of part
 2 IV of subchapter A of chapter 1 of the Internal Rev-
 3 enue Code of 1986 is amended by adding at the end
 4 the following new item:

“Sec. 45E. Credit for medical research related to developing vac-
 cines against widespread diseases.”.

5 (f) EFFECTIVE DATE.—The amendments made by
 6 this section shall apply to taxable years ending after the
 7 date of the enactment of this Act.

8 (g) STUDY.—

9 (1) IN GENERAL.—The National Institutes of
 10 Health shall conduct a study of the extent to which
 11 the credit under section 45E of the Internal Revenue
 12 Code of 1986, as added by subsection (a), has stim-
 13 ulated vaccine research.

14 (2) REPORT.—Not later than the date that is
 15 5 years after the date of the enactment of this Act,
 16 the National Institutes of Health shall submit to
 17 Congress the results of the study conducted under
 18 paragraph (1), together with recommendations (if
 19 any) to improve the effectiveness of such credit in
 20 stimulating vaccine research.

21 **SEC. 3. CREDIT FOR CERTAIN SALES OF LIFESAVING VAC-**
 22 **CINES.**

23 (a) IN GENERAL.—Subpart D of part IV of sub-
 24 chapter A of chapter 1 of the Internal Revenue Code of

1 1986 (relating to business related credits), as amended by
 2 section 2, is amended by adding at the end the following
 3 new section:

4 **“SEC. 45F. CREDIT FOR CERTAIN SALES OF LIFESAVING**
 5 **VACCINES.**

6 “(a) IN GENERAL.—For purposes of section 38, the
 7 lifesaving vaccine sale credit determined under this section
 8 with respect to a taxpayer for the taxable year is an
 9 amount equal to the amount of qualified vaccine sales for
 10 the taxable year.

11 “(b) QUALIFIED VACCINE SALES.—For purposes of
 12 this section—

13 “(1) IN GENERAL.—The term ‘qualified vaccine
 14 sales’ means the aggregate amount paid to the tax-
 15 payer for a qualified sale.

16 “(2) QUALIFIED SALE.—

17 “(A) IN GENERAL.—The term ‘qualified
 18 sale’ means a sale of a qualified vaccine—

19 “(i) to a nonprofit organization or to
 20 a government of any foreign country (or
 21 instrumentality of such a government), and

22 “(ii) for distribution in a developing
 23 country.

24 “(B) DEVELOPING COUNTRY.—For pur-
 25 poses of this paragraph, the term ‘developing

1 country' means a country which the Secretary
2 determines to be a country with a lower middle
3 income or less (as such term is used by the
4 International Bank for Reconstruction and De-
5 velopment).

6 “(3) QUALIFIED VACCINE.—The term ‘qualified
7 vaccine’ means any vaccine and microbicide—

8 “(A) which is described in section
9 45E(b)(2), and

10 “(B) which is approved as a new drug
11 after the date of the enactment of this para-
12 graph by—

13 “(i) the Food and Drug Administra-
14 tion,

15 “(ii) the World Health Organization,
16 or

17 “(iii) the appropriate authority of a
18 country included in the list under section
19 802(b)(1) of the Federal Food, Drug, and
20 Cosmetic Act.

21 “(c) LIMIT ON AMOUNT OF CREDIT.—The maximum
22 amount of the credit allowable under subsection (a) with
23 respect to a sale shall not exceed the portion of the limita-
24 tion amount allocated under subsection (d) with respect
25 to such sale.

1 “(d) NATIONAL LIMITATION ON AMOUNT OF CRED-
2 ITS.—

3 “(1) IN GENERAL.—Except as provided in para-
4 graph (3), there is a lifesaving vaccine sale credit
5 limitation amount for each calendar year equal to—

6 “(A) \$100,000,000 for each of years 2002
7 through 2006, and

8 “(B) \$125,000,000 for each of years 2007
9 through 2010.

10 “(2) ALLOCATION OF LIMITATION.—

11 “(A) IN GENERAL.—The limitation amount
12 under paragraph (1) shall be allocated for any
13 calendar year by the Administrator of the
14 United States Agency for International Devel-
15 opment (referred to in this section as the ‘Ad-
16 ministrator’) among organizations with an ap-
17 plication approved by the Administrator in ac-
18 cordance with subparagraph (B).

19 “(B) APPLICATION FOR ALLOCATION.—
20 The Administrator shall prescribe the proce-
21 dures for an application for an allocation under
22 this subsection and the factors to be taken into
23 account in making such allocations. Such appli-
24 cations shall be made at such time and in such
25 form and manner as the Administrator shall

1 prescribe and shall include a detailed plan for
2 distribution of the vaccine.

3 “(3) CARRYOVER OF UNUSED LIMITATION.—If
4 the limitation amount under paragraph (1) for any
5 calendar year exceeds the aggregate amount allo-
6 cated under paragraph (2), such limitation for the
7 following calendar year shall be increased by the
8 amount of such excess. No amount may be carried
9 under the preceding sentence to any calendar year
10 after 2020.

11 “(e) SPECIAL RULES.—For purposes of this section,
12 rules similar to the rules of section 41(f)(2) shall apply.”.

13 (b) INCLUSION IN GENERAL BUSINESS CREDIT.—

14 (1) IN GENERAL.—Section 38(b) of the Internal
15 Revenue Code of 1986 (relating to current year
16 business credit), as amended by section 2(b), is
17 amended by striking “plus” at the end of paragraph
18 (13), by striking the period at the end of paragraph
19 (14) and inserting “, plus”, and by adding at the
20 end the following new paragraph:

21 “(15) the lifesaving vaccine sale credit deter-
22 mined under section 45F.”.

23 (2) TRANSITION RULE.—Section 39(d) of such
24 Code (relating to transitional rules), as amended by

1 section 2(b), is amended by adding at the end the
 2 following new paragraph:

3 “(11) NO CARRYBACK OF SECTION 45F CREDIT
 4 BEFORE ENACTMENT.—No portion of the unused
 5 business credit for any taxable year which is attrib-
 6 utable to the lifesaving vaccine sale credit deter-
 7 mined under section 45F may be carried back to a
 8 taxable year ending before the date of the enactment
 9 of section 45F.”.

10 (c) CLERICAL AMENDMENT.—The table of sections
 11 for subpart D of part IV of subchapter A of chapter 1
 12 of the Internal Revenue Code of 1986, as amended by sec-
 13 tion 2(c), is amended by adding at the end the following
 14 new item:

“Sec. 45F. Credit for certain sales of lifesaving vaccines.”.

15 (d) EFFECTIVE DATE.—The amendments made by
 16 this section shall apply to sales of vaccines after December
 17 31, 2001, in taxable years ending after such date.

18 **SEC. 4. LIFESAVING VACCINE PURCHASE FUND.**

19 (a) PURPOSE.—It is the purpose of this section to—

20 (1) create incentives for private sector research
 21 into vaccines for HIV, malaria, tuberculosis, and
 22 other major infectious diseases; and

23 (2) ensure that vaccines for major infectious
 24 diseases are affordable and widely distributed.

25 (b) DEFINITIONS.—In this section:

1 (1) DEVELOPING COUNTRY.—The term “devel-
2 oping country” means a country which the Inter-
3 national Bank for Reconstruction and Development
4 (commonly referred to as the “World Bank”) deter-
5 mines to be a country with a lower middle income
6 or less.

7 (2) ELIGIBLE VACCINE.—The term “eligible
8 vaccine” has the meaning given the term “qualified
9 vaccine” in section 45F(b)(3) of the Internal Rev-
10 enue Code of 1986, as added by section 3(a).

11 (c) ESTABLISHMENT OF FUND.—As of the date that
12 the Secretary of the Treasury (referred to in this section
13 as the “Secretary”) determines that any eligible vaccine
14 is available for purchase, there is established in the Treas-
15 ury of the United States a fund to be known as the “Life-
16 saving Vaccine Purchase Fund” (referred to in this sec-
17 tion as the “Fund”) consisting of amounts appropriated
18 under subsection (f).

19 (d) INVESTMENT OF FUND.—Amounts in the Fund
20 shall be invested in accordance with section 9702 of title
21 31, United States Code, and any interest on, and proceeds
22 from any such investment shall be credited to and become
23 part of the Fund.

24 (e) USE OF FUND.—

1 (1) IN GENERAL.—The Secretary is authorized
 2 to expend amounts in the Fund for purchases of eli-
 3 gible vaccines. Such vaccines shall be distributed to
 4 developing countries.

5 (2) PURCHASE AND DISTRIBUTION OF VAC-
 6 CINES.—

7 (A) PURCHASE PRICES, ETC.—Vaccines
 8 purchased by the Fund—

9 (i) shall be purchased at prices which
 10 take into account the seller's research, de-
 11 velopment, and manufacturing costs and
 12 the desirability of the vaccine purchased;
 13 and

14 (ii) shall be purchased under a fund-
 15 ing formula establishing a minimum price
 16 per dose and minimum technical require-
 17 ments and a market test requirement for
 18 the eligible vaccine.

19 (3) DISTRIBUTION.—Eligible vaccines pur-
 20 chased by the Fund shall be distributed to devel-
 21 oping countries under agreements between the
 22 United States Agency for International Development
 23 and international organizations or recipient devel-
 24 oping countries that provide for—

1 (A) consideration of the prevalence of the
2 disease treated by the eligible vaccine in the re-
3 cipient developing country;

4 (B) consideration of the ability of the re-
5 cipient developing country to effectively and
6 safely deliver the vaccines; and

7 (C) a required matching payment by the
8 recipient developing country based on the per
9 capita income of the country, in an amount not
10 in excess of 25 percent of the purchase price
11 paid for such vaccine.

12 (4) REGULATIONS.—The Secretary shall pro-
13 mulgate such regulations as are necessary to carry
14 out the provisions of this subsection.

15 (5) CONSULTATION.—The Secretary shall pro-
16 mulgate regulations under paragraph (4) after ex-
17 tensive consultation with—

18 (A) the International Bank for Reconstruct-
19 ion and Development (commonly referred to as
20 the “World Bank”);

21 (B) the World Health Organization; and

22 (C) the Secretary of Health and Human
23 Services.

24 (f) APPROPRIATIONS.—

1 (1) IN GENERAL.—Subject to paragraph (2),
 2 there are appropriated out of any funds in the
 3 Treasury not otherwise appropriated such sums as
 4 may be necessary to carry out the purposes of the
 5 Fund for each of 10 fiscal years beginning with the
 6 first fiscal year after the date that the Secretary de-
 7 termines that any eligible vaccine is available for
 8 purchase by the Fund.

9 (2) TRANSFER TO FUND.—The Secretary shall
 10 transfer the amount appropriated under paragraph
 11 (1) for a fiscal year to the Fund.

12 (3) AVAILABILITY.—Amounts appropriated
 13 under this section shall remain available without fis-
 14 cal year limitation until expended.

15 **SEC. 5. SENSES OF CONGRESS.**

16 It is the sense of Congress that the following issues
 17 exist:

18 (1) MANUFACTURING CAPACITY.—Delivery of
 19 vaccines to developing country populations is often
 20 delayed a decade or more after these products are li-
 21 censed for use in industrialized nations. This delay
 22 is due partly to inadequate manufacturing capacity
 23 that limits supply of vaccines in the early years of
 24 their distribution. The public sector has a role to
 25 play in ensuring that manufacturing capacity for

1 vaccines for the priority diseases referred to in sec-
2 tion 45E(b)(2) of the Internal Revenue Code of
3 1986, as added by section 2, is sufficient to secure
4 access to these vaccines simultaneously in industri-
5 alized and developing countries. It is appropriate for
6 the Federal Government to consider a variety of
7 mechanisms in order to ensure adequate manufac-
8 turing capacity to meet this goal. These mechanisms
9 may include loan programs, accelerated depreciation,
10 revenue bonds, or infrastructure grants.

11 (2) DISTRIBUTION OF VACCINES DEVELOPED
12 USING CREDIT.—Given the important goal of ensur-
13 ing that all those in need, in both industrialized and
14 developing countries, reap the benefits of any vac-
15 cine or microbicide that is developed for HIV, tuber-
16 culosis, or malaria, and acknowledging the impor-
17 tance of intellectual property rights and the right of
18 corporations and shareholders of corporations to set
19 prices, retain patent ownership, and maintain con-
20 fidentiality of privileged information, corporations
21 and shareholders of corporations who elect to take
22 the credit under section 45E of the Internal Revenue
23 Code of 1986, as so added, for research expenses in-
24 curred in the development of a vaccine or
25 microbicide shall certify to the Secretary of the

1 Treasury that, not later than the date which is 1
 2 year after the date on which the vaccine or
 3 microbicide is first licensed, such corporation will es-
 4 tablish a plan to maximize distribution of such vac-
 5 cine or microbicide in the developing world using
 6 such mechanisms as technology transfer, differential
 7 pricing, and in-country production where possible, or
 8 other mechanisms to maximize international access
 9 to high quality and affordable vaccines.

10 (3) CONTINUED SUPPORT OF GLOBAL EF-
 11 FORTS.—The Federal Government should continue
 12 supporting the work of the Global Alliance for Vac-
 13 cines and Immunizations and the Global Fund for
 14 Children’s Vaccines as an appropriate and effective
 15 vehicle to purchase and distribute these vaccines at
 16 an affordable price once they are discovered in order
 17 to distribute them to the developing world, as it does
 18 with vaccines against hepatitis-B, haemophilus influ-
 19 enza, and yellow fever.

20 (4) TIERED PRICING.—Flexible or differential
 21 pricing for vaccines, providing lowered prices for the
 22 poorest countries, is one of several valid strategies to
 23 accelerate the introduction of vaccines in developing
 24 countries.

